ISRCTN83587695 https://doi.org/10.1186/ISRCTN83587695

A multicenter randomised study comparing the efficacy of adefovir dipivoxil versus pegylated interferon alpha-2a plus placebo versus adefovir dipivoxil plus peglyated interferon alpha-2a for the treatment of chronic delta hepatitis

Submission date
03/08/2005

Recruitment status
No longer recruiting

Registration date
09/09/2005

Overall study status
Completed

Last Edited
02/02/2011

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3388

Study information

Scientific Title

Acronym
Delta Study

Study objectives
Peg-interferon alpha-2a or adefovir lead to sustained virological response in 20-40% of the cases in chronic delta hepatitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Adults with chronic delta hepatitis

Interventions
A: Adefovir dipivoxil, 10 mg, orally (po) for 48 weeks
versus
B: Pegylated interferon alpha-2a, 180 µg subcutaneously (sc), plus placebo for 48 weeks
versus

C: Pegylated interferon alpha-2a, 180 µg sc, plus adefovir dipivoxil, 10 mg po for 48 weeks; biopsy at the end of treatment

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Peg-interferon alpha-2a, adefovir dipivoxil

Primary outcome measure
Response rate of normal ALT and HDV RNA negativity at the end of treatment (ETR)

Secondary outcome measures
1. Response rate of normal ALT and HDV RNA negativity at the end of follow-up (EOF)
2. Suppression of hepatitis B virus (HBV) DNA below 1x10^5 copies/ml at ETR and EOF
3. Paired biopsy comparison
4. HBsAg levels, loss of HBsAg and HBs Antibodies at ETR and EOF
5. HBV and HDV specific T cell response
6. Saftey (adverse events, vital signs, clinical laboratory parameters)

Overall study start date
01/04/2004

Completion date
01/10/2004

Eligibility

Key inclusion criteria
1. Age >18 years
2. Positive Hepatits B surface Antigen (HBsAg)
3. Positive anti-hepatitis D virus (HDV) antibodies
4. Positive HDV-Ribonucleic Acid (RNA) by Polymerase Chain Reaction (PCR)
5. Serum alanine aminotransferase (ALT) >upper limit of normal (ULN) but <10 x ULN
6. Liver biopsy demonstrating liver disease consistent with chronic heaptitis
7. Liver imaging for patients with cirrhosis or marked fibrosis to rule out hepatic carcinoma
8. Negative urine or serum pregnancy test
9. Willingness to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
69

Key exclusion criteria
1. Antiviral therapy in previous six months
2. Positive tests for hepatitis A virus (HAV) Immunoglobulin M (IgM) antibodies, hepatitis C virus (HCV) RNA or HCV antibodies or Human Immunodeficiency Virus (HIV) antibodies
3. Serum total bilirubin >2 x ULN
4. Decompensated liver disease Child B-C
5. Other reasons for chronic liver disease
6. Haemoglobin <11.5 g/dl for females and <12.5 g/dl for males
7. White blood cell count (WBC) <3000 cells/mm^3
8. Serum creatinine >1.5 x ULN
9. Relevant psychiatric diseases
10. Drug or alcohol abuse within one year of entry
11. Other evidence or histroy of severe illness
12. Thyroid disease poorly controlled
13. Alphafetoprotein (AFP) >100 ng/ml

Date of first enrolment
01/04/2004

Date of final enrolment
01/10/2004

Locations

Countries of recruitment
Germany

Study participating centre
Medizinische Hochschule Hannover
Hannover
Germany
30625

Sponsor information

Organisation
Hannover Medical School (MHH) (Germany)

Sponsor details

Kompetenznetz Hepatitis (Hep-Net e.V.)
Department for Gastroenterology, Hepatology and Endocrinology
Carl-Neuberg-Str. 1
Hannover
Germany
30625

Sponsor type
University/education

Website
http://www.kompetenznetz-hepatitis.de

ROR
https://ror.org/00f2yqf98

Funder(s)

Funder type
University/education

Funder Name
Network of competence for hepatitis (Kompetenznetz Hepatitis [Hep-Net e.V.]), c/o Hannover Medical School (Medizinische Hochschule Hannover [MHH]) (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/01/2011		Yes	No